4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0995]

Ivax Pharmaceuticals, Inc.; Withdrawal of Approval of an Abbreviated New Drug Application for Chloramphenicol Capsules, 250 Milligrams

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing the approval of abbreviated new drug application (ANDA) 062247 for chloramphenicol capsules, 250 milligrams (mg), held by Ivax Pharmaceuticals, Inc. (Ivax). Ivax requested withdrawal of this application and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Nikki Mueller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6280, Silver Spring, MD 20993-0002, 301-796-3601.

SUPPLEMENTARY INFORMATION: On April 28, 1980, FDA approved ANDA 062247 for chloramphenicol capsules, 250 mg, an antibiotic indicated to treat only serious infections for which less potentially dangerous drugs are ineffective or contraindicated. CHLOROMYCETIN (chloramphenicol) Capsules, 250 mg (ANDA 060591), was the basis of submission for Ivax's ANDA 062247 for chloramphenicol capsules, 250 mg. In a *Federal Register* notice dated July 13, 2012 (77 FR 41412), FDA determined under 21 CFR 314.161 that CHLOROMYCETIN (chloramphenicol) Capsules, 250 mg (ANDA 060591), was withdrawn for safety reasons and that additional nonclinical and possibly clinical studies of safety and efficacy would be necessary before CHLOROMYCETIN (chloramphenicol) Capsules, 250 mg, could be considered for

reintroduction to the market. The holders of approved applications for chloramphenicol capsules, 250 mg, had ceased marketing of the drug products before July 13, 2012.

On March 29, 2013, Ivax requested that FDA withdraw approval of ANDA 062247 for chloramphenicol capsules, 250 mg. On June 17, 2021, Ivax requested that FDA withdraw approval of ANDA 062247 for chloramphenicol capsules, 250 mg, specifically under § 314.150(d) (21 CFR 314.150(d)) and waived its opportunity for a hearing. For the reasons discussed above, and pursuant to the application holder's request under 314.150(d), approval of ANDA 062247 for chloramphenicol capsules, 250 mg, and all amendments and supplements thereto, is withdrawn under § 314.150(d). Distribution of chloramphenicol capsules, 250 mg, into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d))).

Dated: July 20, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-16077 Filed: 7/26/2022 8:45 am; Publication Date: 7/27/2022]